K090696

510(k) Summary of Safety & Effectiveness **Date: June 15, 2009**

JUN 19 2009

Submitter Name & Address:	Corventis, Inc. 2226 N. First Street San Jose, CA 95131
Contact Person:	Madhuri Bhat, VP, Clinical & Regulatory Affairs 408-790-9306 (phone) 408-790-9350 (fax)
Trade/Proprietary Name:	NUVANT™ Cardiac Event Monitor System NUVANT™ Mobile Cardiac Telemetry System
Common/Usual Name:	Cardiac Event Monitor Mobile Cardiac Telemetry
Classification Name:	Arrhythmia Detector and Alarm (21 CFR 870.1025, Product Code DSI) Patient Physiological Monitor (with arrhythmia detection) (21 CFR 870.1025, Product Code MHX)
Class:	Class II, Special Controls
510(k):	Special 510(k): Device Modification

Predicate Devices:

1. AVIVO Mobile Patient Management System, Corventis, Inc., cleared by FDA under 510(k) number K083287; 21 CFR 870.1025, DSI "Arrhythmia Detector and Alarm", and 21 CFR 870.1025, MHX "Patient Physiological Monitor (with arrhythmia detection)"

2. E-Tac EX-1000 electrocardiographic Event Recorder, Datrix, Inc., cleared by FDA under 510(k) number K042022; 21 CFR 870.2920, DXH "Telephone electrocardiographic transmitter and receiver"

3. SJM Confirm Model DM2100 Implantable Cardiac Monitor and Model DM 2100A Patient Activator, St. Jude Medical, CRMD, cleared by FDA under 510(k) number K081365; 21 CFR 870.2800, MXC "Recorder, Event, Implantable Cardiac, (Without Arrhythmia Detection)"

4. Cardionet Ambulatory ECG Monitor with Arrhythmia Detections, Model CN1004, Cardionet, Inc., cleared by FDA under 510(k) number K063222; CFR 870.1025, DSI "Arrhythmia Detector and Alarm"

Indication for Use Statement:

The NUVANT™ Cardiac Event Monitor (CEM) System and the NUVANT™ Mobile Cardiac Telemetry (MCT) System are intended to continuously measure, record and periodically transmit physiological data. The Systems are indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. Both NUVANT system models monitor, derive and display:

- ECG
- Heart Rate

The Systems may also monitor, derive and display:

- Activity
- Posture
- Respiration rate (including RR variability)
- Body fluid status
- Heart rate variability

Technological Characteristics and Substantial Equivalence

The NUVANT™ Cardiac Event Monitor System and the NUVANT™ Mobile Cardiac Telemetry System include the following components:

- PiiX™ (a patient worn adherent device) with Magnet
- zLink
- Server

The PiiX is a patient-worn device which is applied to the patient's torso. The Adherent Device monitors the patient's ECG in a looping mode. There are three circumstances under which the ECG data will be recorded: (i) when the device is first applied and activated, a baseline ECG is collected, (ii) when the detection algorithms residing in the Adherent Device trigger the collection, or (iii) when the patient activates the collection using the magnet. When the ECG collection is triggered, a total of 45 seconds of ECG signals will be collected, with 15 seconds of pre-event and 30 seconds post-event. Same as the AVIVO™ Mobile Patient Management System (predicate device), the PiiX has additional sensors which monitor other physiological parameters described in the Indications for Use Statement. The collected ECG signals and the other sensor data will be transmitted to the Server via the zLink.
The zLink receives information from the PiiX and transmits them to the Corventis Server. It also interacts with the Corventis Server to receive configuration updates and other relevant hardware diagnostic information.

The Server of the CEM/MCT receives information from the PiiX via zLink. The secure server performs the following functions:

- Derive physiological parameters using the raw data collected by the Adherent Device.
- Display the physiological parameters in trend graphs format.
- Display ECG waveform when the heart rates are beyond the specified threshold.
- Provide visual notifications when healthcare professionals need to be aware of heart rates that are beyond the specified threshold.
- Provide the users the ability to select CEM vs. MCT prescription.
- Provide the users the ability to acknowledge or dismiss events.

The communication between the PiiX and the zLink is enabled via the BlueTooth™ Technology. The zLink transmits the data to the Server via cellular technology, where healthcare professionals can access with standard browsers.

Four (4) predicate devices have been identified for the various aspects of the CEM System and MCT System. They are:

1. AVIVO Mobile Patient Management System, Corventis, Inc., cleared by FDA under 510(k) number K083287; 21 CFR 870.1025, DSI "Arrhythmia Detector and Alarm", and 21 CFR 870.1025, MHX "Patient Physiological Monitor (with arrhythmia detection)"

2. E-Tac EX-1000 electrocardiographic Event Recorder, Datrix, Inc., cleared by FDA under 510(k) number K042022; 21 CFR 870.2920, DXH "Telephone electrocardiographic transmitter and receiver"

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Comparables	Predicate Devices for CEM	Predicate Devices for MCT
Patient Trigger Feature	E-Tac EX-1000 electrocardiographic Event Recorder (K042022)	
Mechanism of the Patient Trigger Feature	SJM Confirm Model DM2100 Implantable Cardiac Monitor and Model DM 2100A Patient Activator (K081365)	
All Other Features	AVIVO Mobile Patient Management System (K083287)	
Overall Product	E-Tac EX-1000 electrocardiographic Event Recorder (K042022)	Cardionet Ambulatory ECG Monitor with Arrhythmia Detections, Model CN1004 (K063222)

Conclusions

The NUVANT™ Cardiac Event Monitor (CEM) System and the NUVANT™ Mobile Cardiac Telemetry (MCT) System models have the same intended use, similar operating principles and technological characteristics as their predicate devices. As supported by the descriptive information and the design verification tests, it is concluded that the NUVANT™ Cardiac Event Monitor (CEM) System and the NUVANT™ Mobile Cardiac Telemetry (MCT) System are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2009

Corventis, Inc.
c/o Ms. Dawn Chang
Senior Regulatory Affairs Associate
2226 N. First Street
San Jose, CA 95131

Re: K090696
Trade/Device Name: NUVANT™ Cardiac Event Monitor System, and
NUVANT™ Mobile Cardiac Telemetry System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (Two)
Product Code: DSI
Dated: May 19, 2009
Received: May 20, 2009

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090696

Indications for Use

510(k) Number (if known): ~~N/A~~ K090696

Device Names: NUVANT™ Cardiac Event Monitor System
NUVANT™ Mobile Cardiac Telemetry System

Indications for Use:

The NUVANT™ Cardiac Event Monitor (CEM) System and the NUVANT™ Mobile Cardiac Telemetry (MCT) System are intended to continuously measure, record, and periodically transmit physiological data. The Systems are indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. Both NUVANT system models monitor, derive and display:

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- Body fluid status
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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090696